

PATENT COOPERATION TREATY

Nederlandsch Octroobureau

INGEK. 19 MRT 2004

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PAYS-BAS

preliminary examination report

rapporten aan dekant

17-4-'04

termijn omzetten in reg./nat. fase:

19-12-'04

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)Date of mailing
(day/month/year)

17.03.2004

Applicant's or agent's file reference
P045311PCT NGA/Jo

IMPORTANT NOTIFICATION

International application No.
PCT/NL 03/00448International filing date (day/month/year)
19.06.2003Priority date (day/month/year)
19.06.2002

Applicant

N.V. NUTRICIA et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 35(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:

European Patent Office
D-80299 Munich
Tel. +49 89 2399-0 Tx: 623656 epmu d
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Authorized Officer

Hutterer, G

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Form PCT/PEA/416 (January 2004)

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P045911PCT NGA/dg		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/NL 03/00448	International filing date (day/month/year) 19.06.2003	Priority date (day/month/year) 19.06.2002	
International Patent Classification (IPC) or both national classification and IPC A61K31/195			
Applicant N.V. NUTRICIA et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(II) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 05.08.2003		Date of completion of this report 17.03.2004	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4485		Authorized Officer Groh, B Telephone No. +49 89 2399-7885 	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. , PCT/NL 03/00448.

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*);

Description, Pages

1-22

as originally filed

Claims, Numbers

1-17

as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form,
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages;
- ☐ the claims, Nos.;
- ☐ the drawings, sheets;

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**International application No. **PCT/NL 03/00448****V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement****1. Statement**

Novelty (N)

Yes: Claims 1-17

No: Claims

Inventive step (IS)

Yes: Claims 1-17

No: Claims

Industrial applicability (IA)

Yes: Claims 1-17

No: Claims

2. Citations and explanations

see separate sheet

INTERNATIONAL PRELIMINARY

International application No. PCT/NL03/00448

EXAMINATION REPORT - SEPARATE SHEET**Re Item V****Patentability**

The claims 15 - 17 also refer to a therapeutic method.

These claims may not be patentable for some states, or group of states, contracted within the PCT, such as the EPC.

Clarity (Art. 6 PCT)

Claims defined by using expressions such as "... (X) and the equivalents thereof .." is ~~generally considered to be not clear. In the present case the description provides a~~ detailed definition of what is meant by "...equivalents of ...", see p. 12.

It is considered that claim 1, in the light of the description, meets Art. 6 PCT.

Novelty (Art. 33(2) PCT)

Glycocyamine is known to be a precursor to creatine (which is used to provide energy in muscles).

Further, it is known that glycocyamine can be methylized in vivo into creatine, which results in beneficiary effects in the muscle tissue and the nervous system (see GB 696405 & EP 0532369)

However, pharmaceutical or nutritional compositions, which contain a combination of glycocyamine and protein or peptides, which contain L-serine, are new.

Inventive step (Art. 33(3) PCT)

It is known that glycocyamine can be methylized in vivo into creatine. This methylation can be supported by choline, betaine, betaine hydrate, dimethyl threine or methionine (see GB 696 405).

However, there is no indication in the relevant prior art, that the (*non-essential*)-amino acid L-serine could be efficiently supporting the in vivo methylation of glycocyamine to creatine.

All claims appear to be novel and inventive over the prior art, as reflected in the search report.

Industrial application

is given in the application, for example as muscle performance enhancer.

INTERNATIONAL SEARCH REPORT

 Inventor Application No
 PCT/NL 03/00448

 A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K31/195 A23L1/305

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

 Minimum documentation searched (classification system followed by classification symbols)
 IPC 7 A61K A23L C07C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, FSTA, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 696 405 A (CALIFORNIA INST RES FOUNDATION) 26 August 1953 (1953-08-26) column 1, line 17 - column 2, line 69	1, 5, 13, 17
A	WO 91 07954 A (DIOGUARDI FRANCESCO SAVERIO) 13 June 1991 (1991-06-13) claims 1-5	1, 5, 13
A	US 5 767 159 A (HARRIS ROGER C ET AL) 16 June 1998 (1998-06-16) claims 1, 7	1, 13
A	EP 0 532 369 A (BISSBORT SIEGBERT HEINRICH ; DAVIS HENRY JOHN (ZA)) 17 March 1993 (1993-03-17) claims 1-19, 22	1-5, 8-17

-/-

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claim(s)

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other cited documents, such combination being obvious to a person skilled in the art
- *Z* document member of the same patent family

Date of the actual compilation of the international search

22 August 2003

Date of mailing of the international search report

28/08/2003

 Name and mailing address of the ISA
 European Patent Office, P.O. Box 5016 Patentplan 2
 NL-2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
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Authorized officer

Groh, B

Form PCT/ISA/210 (second sheet) (July 1992)

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INTERNATIONAL SEARCH REPORT

Intern Application No
PCT/NL 03/00448

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 871 550 A (MILLMAN PHILLIP L) 3 October 1989 (1989-10-03) claim 1	1, 13, 14

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

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INTERNATIONAL SEARCH REPORT

In international application No.
PCT/NL 03/00448

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15 (partially) - 17 (partially)
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1998)

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INTERNATIONAL SEARCH REPORT

 Inter I Application No
 PCT/NL 03/00448

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
GB 696408	A	26-08-1953	NONE	
WO 9107954	A	13-06-1991	IT AU WO EP	1237519 B 6732190 A 9107954 A1 0455770 A1
				08-06-1993 26-06-1991 13-06-1991 13-11-1991
US 5767159	A	16-06-1998	AU AU CA EP FI JP NO NZ WO	678559 B2 4594893 A 2140768 A1 0652748 A1 950302 A 7509230 T 950250 A 254307 A 9402127 A1
				05-06-1997 14-02-1994 03-02-1994 17-05-1995 24-01-1995 12-10-1995 23-01-1995 20-12-1996 03-02-1994
EP 0532369	A	17-03-1993	AP AT AU AU CA DE EP IL US	387 A 244005 T 666490 B2 2352792 A 2078019 A1 69233115 D1 0532369 A2 103152 A 5545670 A
				31-07-1995 15-07-2003 15-02-1996 18-03-1993 14-03-1993 07-08-2003 17-03-1993 16-08-1998 13-08-1996
US 4871550	A	03-10-1989	EP	0259167 A2
				09-03-1988

Form PCT/ISA/210 (patent family annex) (July 1992)

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